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EXAMINER	
BRISTOL, LYNN ANNE	
ART UNIT	PAPER NUMBER
1643	

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
31 DAYS	04/12/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No.	Applicant(s)	
	10/524,787	EISENBACH ET AL.	
	Examiner	Art Unit	
	Lynn Bristol	1643	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-61 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) 1-61 are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. Claims 1-61 are all the pending claims subject to lack of unity restriction and election of species requirement.

2. The claims are drawn to several distinct and separate antigenic peptides/epitopes derived from different tumor-associated antigens. Applicants specification teaches that STEAP and PSGR are prostate-restricted antigens ([0016]), and human 1-8D interferon inducible gene, actin binding protein, human ribosomal protein L23a, TGF beta induced gene and human TB2 gene are colon-cancer restricted antigens ([0044]; Table 3):

a) SEQ ID NO:41 (STEAP-3)

b) SEQ ID N0:49 (PSGR 1)

c) SEQ ID NO:50 (PSGR 2)

d) SEQ ID NO:51 (PSGR 3)

e) SEQ ID NO:52 (PSGR 4)

f) SEQ ID NO:53 (PSGR 5)

g) SEQ ID NO:54 (PSGR 6)

h) SEQ ID NO:55 (PSGR 7)

i) SEQ ID N0:27 (protein for human 1-8D interferon inducible gene)

j) SEQ ID NO:16 (actin binding protein)

k) SEQ ID NO:20 (human ribosomal protein L23a)

l) SEQ ID NO:21 (TGF beta induced gene)

m) SEQ ID NO:22 (human TB2 gene)

As discussed below, because each of the peptides is patentably distinct, Applicants are requested to elect a single peptide for examination on the merits.

3. It is noted that for generic Claim 1, element (A) is drawn to human colon carcinoma cells whereas element (B) (second occurrence) is a Markush group reciting peptides which are all derived from prostate tumors. Because both elements (A) and (B) (second occurrence) appear to be required for the peptide of Claim 1 (and the dependent claims thereof), and the specification teaches that the peptides of the invention are distinctly derived from prostate or colon cancers, it is not clear how the claimed features can be overlapping, absent á showing to the contrary. Clarification is requested.

Lack of Unity: Restriction

4. Restriction is required under 35 U.S.C. 121 and 372.

The claims of the present application relate to peptides obtainable from prostate specific G protein-coupled receptor (PSGR), six-transmembrane epithelial antigen of prostate (STEAP) and proteins encoded by genes found overexpressed in colon carcinoma cells, such as human 1-8D interferon induced transmembrane protein 2 (1-8D), actin binding protein, human ribosomal protein L23a, TGF beta induced gene, and human TB2 gene. The peptides share the common property of being derived from tumor-associated antigens, and possess MHC Class I binding and CTL-inducing capabilities. Otherwise, the structures of the peptides are not commonly shared nor are the proteins from which they are derived from.

In assessing whether the requirements of unity of invention of an application are met, identification of the technical features that each solution to a technical problem contributes over the prior art (special technical features) must be made. If then a technical relationship between the solutions, involving one or more of the same technical features, can be recognized, the requirements of unity of invention are said to be met.

Antigenic peptides corresponding to the peptide of SEQ ID NO:41 (STEAP-3) were already known before the priority date of the present application. For example, Afar et al. (US2005063975; with priority to USPN 6,833,438 (filed 12/6/99) and USPN 6,329,503 (filed 6/1/99) teaches immunogenic peptides derived from STEAP proteins and having MHC class I and CTL-inducing properties. (See attached sequence search alignment for SEQ ID NO:41).

5. This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1. The resulting separate inventions, as presently identified, have been grouped according to the order in which they have been claimed.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group I, claim(s) 1, 2, 3, 9-23, drawn to a peptide derived from a tumor associated antigen (STEAP) having the properties of MHC class I binding and eliciting CTL induction, pharmaceutical compositions comprising the peptide and pharmaceutical compositions comprising an antigen presenting cell comprising the peptide.

Group II, claim(s) 1; 2, 3, 9, 10, and 12-23, drawn to a peptide derived from a tumor associated antigen (PSGR) having the properties of MHC class I binding and eliciting CTL induction, pharmaceutical compositions comprising the peptide and

pharmaceutical compositions comprising an antigen presenting cell comprising the peptide.

Group III, claim(s) 1-7, 9, 12-23, 30-45 and 59, drawn to a peptide derived from a tumor associated antigen (protein for 1-8D interferon inducible gene) having the properties of MHC class I binding and eliciting CTL induction, pharmaceutical compositions comprising the peptide and pharmaceutical compositions comprising an antigen presenting cell comprising the peptide, and the protein for 1-8D interferon inducible gene.

Group IV, claim(s) 1-3, 8, 9 and 12-23, drawn to a peptide derived from a tumor associated antigen (actin binding protein) having the properties of MHC class I binding and eliciting CTL induction, pharmaceutical compositions comprising the peptide and pharmaceutical compositions comprising an antigen presenting cell comprising the peptide.

Group V, claim(s) 1-3, 8, 9 and 12-23, drawn to a peptide derived from a tumor associated antigen (human ribosomal protein L23a) having the properties of MHC class I binding and eliciting CTL induction, pharmaceutical compositions comprising the peptide and pharmaceutical compositions comprising an antigen presenting cell comprising the peptide.

Group VI, claim(s) 1-3, 8, 9 and 12-23, drawn to a peptide derived from a tumor associated antigen (TGF beta) having the properties of MHC class I binding and eliciting CTL induction, pharmaceutical compositions comprising the peptide and pharmaceutical compositions comprising an antigen presenting cell comprising the peptide.

Group VII, claim(s) 1-3, 8, 9 and 12-23, drawn to peptide derived from a tumor associated antigen (human TB2) having the properties of MHC class I binding and eliciting CTL induction, pharmaceutical compositions comprising the peptide and pharmaceutical compositions comprising an antigen presenting cell comprising the peptide.

Group VIII, claim(s) 24 and 25, drawn to a method of treating or inhibiting colon or prostate cancer comprising a pharmaceutical composition comprising a STEAP-derived peptide.

Group IX, claim(s) 24 and 25, drawn to a method of treating or inhibiting colon or prostate cancer comprising a pharmaceutical composition comprising a PSGR-derived peptide. Should Applicant's elect the method claims, the claims will be examined to the extent they read on the elected PSGR peptide.

Group X, claim(s) 26-29, drawn to a polynucleotide encoding a STEAP peptide.

Group XI, claim(s) 26-29, drawn to a polynucleotide encoding a PSGR peptide. Should Applicant's elect the polynucleotide claims, the claims will be examined to the extent they read on the elected PSGR peptide.

Group XII, claim(s) 30, 46-53, 60 and 61, drawn to a pharmaceutical composition comprising polynucleotides encoding a protein for 1-8D interferon inducible gene and peptides thereof.

Group XIII, claim(s) 53-56, drawn to a method of treating or inhibiting colon cancer with a peptide from a protein for a human 1-8D interferon inducible gene.

Group IVX, claim(s) 53-56, drawn to a method of treating or inhibiting colon cancer with a polynucleotide encoding a peptide from a protein for a human 1-8D interferon inducible gene.

Group VX, claim(s) 57, drawn to a method for treating or inhibiting colon cancer comprising an antibody against the protein for human 1-8D interferon inducible gene.

Group XVI, claim(s) 57, drawn to a method for detecting overexpression of protein for human 1-8D interferon inducible gene comprising an antibody against the human 1-8D interferon inducible gene.

6. As no technical features can be distinguished which, in light of the prior art, could be regarded as special technical features on which a unifying concept could be based, there is no single inventive concept underlying the plurality of claimed inventions.

7. Ten different products are presented in Groups I-VII and X-XII. These ten products share a common property or activity (i.e., encode peptide(s) or comprise peptide(s) that possess MHC Class I binding and CTL-inducing capabilities) but do not share common core structures. None of the peptides require the same exact amino acid sequence. One skilled in the art could not predict what if any biochemical properties, e.g., binding, affinity, etc., were affected by differences in the amino acid sequences for any of the peptides.

Further Groups I-VII are drawn to peptides and Groups X-XII are drawn to polynucleotides encoding the peptides. In the instant case, the polynucleotide claims do not overlap the scope of the peptide claims and vice versa as evidence by the distinct structures and functions of the claimed inventions. A polynucleotide structure is comprised of linear, contiguous nucleotides while a peptide structure is comprised of linear, contiguous amino acids that fold into a specific three-dimensional structure; the polynucleotide function is to encode a protein or peptide while a peptide's function is variable. Additionally, the polynucleotides and peptides are not obvious variants of each other based on the distinct structures and functions of each as noted above. Lastly, the polynucleotides and peptides have materially different functions as noted above.

Because these inventions are distinct for the reasons given above and the search required for Groups I-VII is not required for Groups X-XII, restriction for examination purposes as indicated is proper. Further claims in Groups I-VII, drawn to peptides, must be searched not only in commercial amino acid sequence databases, but also in textual databases because isolated peptides are often disclosed without the benefit of sequence information although the amino acid sequence is inherently the same as the sequence claimed. Additionally, the polynucleotide sequences must be searched in distinct nucleic acid sequence commercial databases. Thus, Groups I-VII and X-XII have been appropriately restricted on the basis of being distinct.

8. Six different methods are presented in Groups VIII, IX and XIII-XVI. These six different methods require different method steps to perform the methods, different reagents to practice the method steps, and each method has a different intended

population to which the endpoint is directed. None of the methods requires the same reagents for obtaining the same intended endpoint or effecting the same intended population. Thus, Groups VIII, IX and XIII-XVI have been appropriately restricted on the basis of being distinct and separate.

9. Groups I and VIII; Groups II and IX; Groups III and XIII; and Groups XII and IVX are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product. See MPEP § 806.05(h). In the instant case, the method of treating or inhibiting colon or prostate cancer can be practiced with a materially different product than the STEAP, PSGR or 1-8D peptides, or a polynucleotide encoding the 1-8D peptide, such as chemotherapy, radiotherapy, anti-sense therapy, small molecule drugs, etc. Thus, Groups I and VIII; Groups II and IX; Groups III and XIII; and Groups XII and IVX have been appropriately restricted on the basis of being distinct and separate.

10. The products of Groups I-VII and X-XII and the method of Group XVI are not disclosed as being capable of use together in the specification.

11. The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and the product claims are subsequently found allowable, withdrawn process claims that depend from or otherwise require all the limitations of the allowable product claim will be considered for rejoinder. All claims directed to a nonelected process invention must require all the limitations of an allowable product claim for that process invention to be rejoined.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the

requirements of 35 U.S.C. 101, 102, 103 and 112. Until all claims to the elected product are found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowable product claim will not be rejoined. See MPEP § 821.04(b). Additionally, in order to retain the right to rejoinder in accordance with the above policy, applicant is advised that the process claims should be amended during prosecution to require the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder**. Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

12. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Election of Species Requirement

13. If any one of Groups VIII or IX are elected, then species (cancer) below must be elected as applicable. This application contains claims (Claims 24 and 25) directed to the following patentably distinct species of the claimed invention:

Specie A) colon cancer

Specie B) prostate cancer

In the instant case the species of cancer can originate from any number of different cell types (e.g., epithelial, mesothelial or endothelial). Also, the cancers being associated with different organs are nevertheless, under the influence of different growth factors, hormones, cytokines, etc., especially whereas prostate cancer is male-

specific, and colon cancer occurrence is between females and males. Additionally, numerous studies have shown that receptor density and affinity for different therapeutic biomolecules is highly variable amongst different tissues and organs, in addition to there being differences to the extent to which biomolecules are able to penetrate tissues and organs. This suggests that any method inventions involving administering a therapeutic in the realm of a cancer, would require different routes of administration, dosing, formulation, sensitivity of detection, etc., and that one could not predict biodistribution of the therapeutic agent in a subject much less an outcome of success for treating all colon and prostate cancers in following the same method steps or conditions.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, Claims 24 and 25 are generic as to Species A and B.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims

are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lynn Bristol whose telephone number is 571-272-6883. The examiner can normally be reached on 8:00-4:00, Monday through Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Larry Helms can be reached on 571-272-0832. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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